

K130172

510(k) Summary

Date: February 28, 2013

Submitter's Name / Address: Belimed, Inc.
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Trade Name: Belimed Steam Sterilizer MST-V

Model: 4-4-6

Classification: Steam Sterilizer – Class II, as listed per 21 CFR 880.6880
Product Code FLE

Predicate Device: Belimed Steam Sterilizer MST-V
Series 3-3-6 (K100662)

SEP 23 2013

DEVICE DESCRIPTION:

The Belimed Steam Sterilizer MST-V, model 4-4-6 is intended for use in hospital and health care facilities and is intended to be used in an identical manner as the Belimed Steam Sterilizer Series 3-3-6.

NONCLINICAL COMPARISON TO THE PREDICATE DEVICE:

The Belimed Steam Sterilizer MST-V, model 4-4-6 is very similar to the predicate device. Modifications made from the predicate device include:

- Larger chamber size
- Control system and HMI (operating panel)
- Modification of gravity cycle parameters (exposure and dry times)
- Change in manufacturing location

CLINICAL DATA:

No clinical data is required for this device classification submission.

INDICATIONS FOR USE:

The Belimed Steam Sterilizer MST-V, model 4-4-6 is designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.

The Belimed Steam Sterilizer MST-V, model 4-4-6 is equipped with the following factory-programmed Sterilization cycles and cycle values (Table 1).

The Belimed Steam Sterilizer MST-V, model 4-4-6 is available with a single door, prevacuum/gravity.

Table 1: Factory programmed Sterilization cycles

No.	CYCLE	PRE-TREATMENT	STERILIZE TEMP / PRESSURE	STERILIZE TIME	DRY TIME ¹	RECOMMENDED LOAD ²
1	PreVac 270 4S / 30Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	4 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray Fabric packs ³
2	PreVac Immediate Use 270 4S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	4 min	1 min	Unwrapped porous or non-porous single instrument or Unwrapped mixed porous and non- porous instrument trays, max. weight of 25 lbs per tray
3	PreVac Immediate Use 270 3S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	3 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
4	PreVac Immediate Use 270 10S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	10 min	1 min	Unwrapped porous or non-porous single instrument or Unwrapped mixed porous and non- porous instrument trays, max. weight of 25 lbs per tray
5	Gravity Immediate Use 270 3S / 1Dry	Purge time 3 min	270 °F 2880mbar	3 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
6	Gravity Immediate Use 270 10S / 1Dry	Purge time 3 min	270 °F 2880mbar	10 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
7	Gravity 270 15S / 30Dry	Purge time 3 min	270 °F 2880mbar	15 min	30 min	Double wrapped non-porous instrument trays, max. weight of 25 lbs per tray
8	Gravity 250 30S / 30Dry	Purge time 3 min	250 °F 2040mbar	30 min	30 min	Double wrapped non-porous instrument trays, max. weight of 25 lbs per tray
9	Bowie-Dick Test	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	273 °F 3030mbar	3.5 min	1 min	One DART or Bowie-Dick-Test-Pack

No.	CYCLE	PRE-TREATMENT	STERILIZE TEMP / PRESSURE	STERILIZE TIME	DRY TIME ¹	RECOMMENDED LOAD ³
10	Leak Test	Vacuum: 100mbar Test time: 15 min	-	-	-	Empty chamber

Notes on Table 1:

1. Factory set dry time is recommended. Extended dry time may be required depending on local conditions and wraps.
2. Recommended load: Refer to table 3 and 4.
3. Fabric load should be preconditioned between 68°F and 75°F and at a relative humidity of at least 35% to 60% for at least 2 hours.

The Belimed Steam Sterilizer MST-V is offered in the following configuration:

Table 2: Dimensions

Model single door double door	Configuration	Chamber size (Volume) (L)	Chamber size (H x W x D)		Overall Dimensions (H x W x D)	
			(inch)	(mm)	(inch)	(mm)
4-4-6	1 door	110	16"x 16"x 26"	406 x 406 x 660	74.75" x 26" x 35.5"	1900 x 660 x 900

Table 3 indicates Belimed's guidelines for recommended loads for the Belimed Steam Sterilizer MST-V:

Table 3: Recommended Loads

Model single door double door	Wrapped instrument trays, max. 25 lbs each	Unwrapped tray with single instrument	Unwrapped instrument tray, max. 25 lbs each	Fabric Packs, max. 6.6 lbs each	Fabric Packs, max. 9 lbs each
4-4-6	2	1	2	4	2

The Belimed Steam Sterilizer MST-V, model 4-4-6 is designed to be used for the terminal sterilization of porous and non-porous, heat and moisture stable materials in healthcare facilities.

Depending of the chosen cycle, materials including textiles, unwrapped or wrapped instrument trays with single or multiple instruments may be sterilized.

The Belimed Steam Sterilizer MST-V, model 4-4-6 is factory equipped with cycles which have been tested in accordance with ANSI/AAMI ST8:2008 under defined load conditions. The predicate device with a chamber volume of 73 liters has been validated previously.

Comparison to Predicate Device

Feature	Belimed MST-V 4-4-6	Belimed MST-V 3-3-6 (Predicate)
Intended Use	Terminal sterilization of non porous and porous heat and moisture-stabile materials. This includes rigid devices with lumens processed in accordance with AAMI ST8.	Terminal Sterilization of non porous and porous heat and moisture-stabile materials. This includes rigid devices with lumens processed in accordance with AAMI ST8.
Designed for	Steam sterilization in health care facilities	Steam sterilization in health care facilities
Design, Construction, Components	Stainless Steel 316L 16" x 16" x 26" (110 l) Design Pressure 40PSI ASME Certified Chamber and Jacket Cubic welded structure with complete jacket (except door and back wall)	Stainless Steel 316L 13" x 13" x 25" (73 l) Design Pressure 40PSI ASME Certified Chamber and Jacket Cubic welded structure with all-round heating ducts
Process monitoring & control devices:	Interactive Touch Panel with 5.7" color display Printer (24 Char/ Line) Pressure Gauges: chamber, jacket, door seal (digital) compressed air, steam supply, chamber pressure, jacket pressure (analog)	Interactive Operating Panel with 5.7" color display (TFT) Printer (42 Char/ Line) Pressure Gauges: chamber, jacket (digital) compressed air, steam supply, door seal (analog)
Safety Devices	Safety Relief Valves Emergency Stop Switch Door safety pressure relief valve	Safety Relief Valves Emergency Stop Switch
Standard Cycles	PreVac 270 4S / 30Dry PreVac Immediate Use 270 4S / 1Dry PreVac Immediate Use 270 3S / 1Dry PreVac Immediate Use 270 10S / 1Dry Gravity Immediate Use 270 3S / 1Dry Gravity Immediate Use 270 10S / 1Dry Gravity 270 15S / 30Dry Gravity 250 30S / 30Dry Bowie-Dick Test Leak Test	PreVac 270 Long Dry (4S, 30D) PreVac 270 Short Dry (4S, 5D) Prevac Flash 270 (4S, 1D) Gravity 250 (25S, 0D) PreVac 270 Long Dry (10S, 30D) PreVac Flash 270 (10S, 1D) Bowie-Dick Test Leak Test Warm up & leak test

EFFECTIVENESS:

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} reduction. Belimed validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI). Prior to release, Belimed Steam Sterilizer MST-V, model 4-4-6 was validated to meet the requirements of ANSI/AAMI ST8:2008.

The results of the Belimed Steam Sterilizer MST-V, model 4-4-6 verification studies demonstrate that the sterilizer performs as intended and is summarized as follows:

- Empty chamber testing performed as described in Section 5.4.2.5 of ANSI/AMMI ST8:2008, for the Prevac, Prevac Immediate Use, and Gravity cycles. These cycles demonstrated the sterilizer's capability to provide steady state thermal conditions within the chamber that correspond with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the requirements of Section 4.4.2.2 and 4.4.2.5 of ANSI/AAMI ST8.
- All Prevac cycles verified using the fabric test pack, as described in Section 5.5.2 ANSI/AAMI ST8:2008 were qualified according to section 5.5.2.5 ANSI/AAMI ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle, moisture retention of less than 3 % increase in pre-sterilization test pack weight, and exhibited no wet spots.
- All Prevac and Gravity cycles verified using full load instruments trays were qualified according to section 5.5.4 of ANSI/AAMI ST8:2008. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle, moisture retention of less than 20% increase in pre-sterilization weight of the towel, and exhibited no wet spots on the outer wrapper.
- All Prevac Immediate Use cycles were verified using unwrapped instrument trays and were qualified according to section 5.5.5.2 ANSI/AAMI ST8:2008. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 of at least 12 minutes by half cycle.
- All Gravity Immediate Use cycles were verified using unwrapped instrument tray and were qualified according to section 5.5.5.1 ANSI/AAMI ST8:2008. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time at temperature sufficient to produce an F_0 of at least 12 minutes by half cycle.
- The Bowie Dick Test cycle was verified using the Bowie-Dick Test Pack was qualified according to section 5.6 of ANSI/AAMI ST8, and demonstrated a uniform color change throughout the test sheet and the load temperature devices attained the exposure temperature within 10 seconds of progressing into the exposure phase.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (May 2005)"*.

SAFETY:

Belimed's sterilizers, including the Belimed Steam Sterilizer MST-V model 4-4-6, have been designed and constructed to meet the safety and performance requirements of various national safety codes and standards. The Belimed Steam Sterilizer MST-V complies with the following safety standards:

1. ANSI/AAMI ST8:2008
2. ANSI/AAMI ST79:2010+A1:2010
3. IEC EN 62304:2006
4. EN ISO 14971:2007
5. ISO 13485:2007 Medical Devices – Quality management systems. Requirements for regulatory purposes
6. IEC EN 60601-1-2:2007
7. American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels Ed. 2007+Addenda 2009

HAZARDS-FAILURE OF PERFORMANCES

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another not otherwise infected prior to the incident.

To avoid failure, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer's manufacturer's maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incident of sterilizer malfunction or sterilization process failure is relatively rare considering the wide spread use of steam sterilizers. Further, there are no known reports in the literature of patient infection that have resulted from steam sterilizer failure. The technology designed in Belimed Steam Sterilizer MST-V provides microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

USER INFORMATION

Belimed provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed User's Manual and other labeling. Belimed also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.

CONCLUSION

The Belimed Steam Sterilizer MST-V, model 4-4-6 is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology and intended use to the predicate device series 3-3-6 (K100662). This steam sterilizer MST-V model 4-4-6 meets the applicable requirements of the applicable standards.

Based on the provided information in this premarket notification, the subject device is substantially equivalent to the predicate device and is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

September 23, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Belimed, Incorporated
Mr. Jay Upchurch
Quality Assurance Manager
2284 Clements Ferry Road
CHARLESTON, SOUTH CAROLINA 29492

Re: K130172
Trade/Device Name: Belimed Steam Sterilizer MST-V, model 4-4-6
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 26, 2013
Received: August 27, 2013

Dear Mr. Upchurch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Richard C.
Chapman
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Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130172

Device Name: Belimed Steam Sterilizer MST-V, model 4-4-6

Indications for Use:

The Belimed Steam Sterilizer MST-V, model 4-4-6 is designed for sterilization of non-porous and porous heat and moisture-stable materials used in healthcare facilities.

The Belimed Steam Sterilizer MST-V, model 4-4-6 is equipped with the following factory-programmed Sterilization cycles and cycle values (Table 1).

The Belimed Steam Sterilizer MST-V, model 4-4-6 is available as a single door prevacuum/gravity version.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒ OTC
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130172

No.	CYCLE	PRE-TREATMENT	STERILIZE TEMP / PRESSURE	STERILIZE TIME	DRY TIME ¹	RECOMMENDED LOAD ²
1	PreVac 270 4S / 30Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	4 min	30 min	Double-wrapped instrument trays, max. weight of 25 lbs per tray or Fabric packs ³
2	PreVac Immediate Use 270 4S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	4 min	1 min	Unwrapped porous or non-porous single instrument or Unwrapped mixed porous and non- porous instrument trays, max. weight of 25 lbs per tray
3	PreVac Immediate Use 270 3S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	3 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
4	PreVac Immediate Use 270 10S / 1Dry	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	270 °F 2880mbar	10 min	1 min	Unwrapped porous or non-porous single instrument or Unwrapped mixed porous and non- porous instrument trays, max. weight of 25 lbs per tray
5	Gravity Immediate Use 270 3S / 1Dry	Purge time 3 min	270 °F 2880mbar	3 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
6	Gravity Immediate Use 270 10S / 1Dry	Purge time 3 min	270 °F 2880mbar	10 min	1 min	Unwrapped non-porous single instrument or Unwrapped non-porous instrument trays, max. weight of 25 lbs per tray
7	Gravity 270 15S / 30Dry	Purge time 3 min	270 °F 2880mbar	15 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray
8	Gravity 250 30S / 30Dry	Purge time 3 min	250 °F 2040mbar	30 min	30 min	Double wrapped instrument trays, max. weight of 25 lbs per tray
9	Bowie-Dick Test	3 vacuum pulses: 100/100/100mbar 2 steam pulses: 1800/1800mbar	273 °F 3030mbar	3.5 min	1 min	One DART or Bowie-Dick Test Pack
10	Leak Test	Vacuum: 100mbar Test time: 15 min	-	-	-	Empty chamber

Notes on Table 1:

1 Factory set dry time is recommended. Extended dry time may be required depending on local conditions and wraps.

2 Recommended loads: Refer to table 3.

3 Fabric load should be preconditioned between 68°F and 75°F and at a relative humidity of at least 35% to 60% for at least 2 hours.

The Belimed Steam Sterilizer MST-V, model 4-4-6 is offered in the following configuration:

Table 2: Dimensions

Model single door double door	Configuration	Chamber size (Volume) (L)	Chamber size (H x W x D)		Overall Dimensions (H x W x D)	
			(inch)	(mm)	(inch)	(mm)
4-4-6	1 door	110	16"x 16"x 26"	406 x 406 x 660	74.75" x 26" x 35.5"	1900 x 660 x 900

The following table (Table 3) provides guidelines for recommended loads in the Belimed Steam Sterilizer MST-V, model 4-4-6:

Table 3: Recommended Loads

Model single door double door	Wrapped instrument trays, max. 25 lbs each	Unwrapped tray with single instrument	Unwrapped instrument tray, max. 25 lbs each	Fabric Packs
4-4-6	2	1	2	4